UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	**MDL No. 1456**
	)	**Master File No. 01-12257-PBS**
	)	**Subcategory Case No. 06-11337**
	)	**Judge Patti B. Saris**
THIS DOCUMENT RELATES TO: *State of California, ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al.* Case No: 1:03-cv-11226-PBS	)	**Magistrate Judge Marianne B. Bowler**

PLAINTIFFS' BRIEF IN OPPOSITION TO DEFENDANT SANDOZ INC.'S MOTION FOR SUMMARY JUDGMENT

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Plaintiffs, the State of California and Ven-A-Care of the Florida Keys, Inc. ("Plaintiffs"), hereby submit the following brief in opposition to the motion for summary judgment filed in this matter by Defendant Sandoz Inc. ("Sandoz") (docket nos. 6697-6698, 6700).

INTRODUCTION

Sandoz filed its separate motion[1] for summary judgment based on two arguments. First, Sandoz argues that Plaintiffs' claims under the California False Claims Act ("CA FCA") (CAL. GOV'T CODE §§ 12650, *et seq.*) are insufficient as a matter of law to impose liability on Sandoz for its reporting of false, and at times grossly inflated, Average Wholesale Prices ("AWPs") to the pricing compendia. Second, Sandoz claims that the statute of limitations bars California's claims that allege damages prior to August 1999. As shown below, neither argument is factually or legally sufficient to support the granting of Sandoz's motion for summary judgment.

LEGAL STANDARD

As this Court recognized in *Massachusetts v. Mylan Labs.* ("*Mylan Labs.*"), 608 F. Supp. 2d 127 (D. Mass. 2008), "'[s]ummary judgment is appropriate when the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.'" *Barbour v. Dynamics Research Corp.*, 63 F.3d 32, 36-37 (1st Cir. 1995), quoting FED. R. CIV. P. 56(c))." (*Mylan Labs.*, 608 F. Supp. 2d at 139.) "To succeed [in a motion for summary judgment], the moving party must show that there is an absence of evidence to support the nonmoving party's position." *Rogers v. Fair*, 902 F.2d 140, 143 (1st Cir. 1990). In assessing whether such showing has been made, the Court must "view the facts in the light most

[1] In addition to Sandoz, Defendants Mylan and Dey have also filed separate motions for partial summary judgment. All three defendants have also filed a joint motion for partial summary judgment, which is based primarily upon the defense of "government knowledge." In opposing the joint brief, Plaintiffs will incorporate by reference the arguments made in the instant brief where applicable.

favorable to the non-moving party, drawing all reasonable inferences in that party's favor." *Barbour*, 63 F.3d at 36.

ARGUMENT

I. Plaintiffs' Claims Under the CA FCA Are Sufficient to Withstand Summary Judgment

Sandoz's position that it is entitled to summary judgment as to Plaintiffs' claims under the CA FCA is based on the argument that because California was in possession of either Average Manufacturer Price ("AMP") information for the Subject Drugs (i.e., the Sandoz drugs at issue in this action) or Unit Rebate Amount ("URA") data received from CMS concerning the Subject Drugs, California had knowledge of the difference between providers' actual acquisition costs for the Subject Drugs and the fraudulent, inflated AWPs Sandoz caused to be published in the pricing compendia. (Defendant Sandoz's Brief in Support of Its Motion for Summary Judgment ("Sandoz SJ Br."), at 1.) Consequently, Sandoz claims, it could not, *as a matter of law*, have acted with the scienter required under the CA FCA. Sandoz appears to further claim that it was open and cooperative with California, in that it "informed [the State] of the very facts upon which [it] claims to have been defrauded." (Sandoz SJ Br. 4.)

These arguments are belied by the actual facts in this case, and seemingly ignore and certainly misinterpret the applicable caselaw.

A. California's Possession of AMP/URA Data is Not Sufficient to Establish Government Knowledge

Sandoz argues that California's possession of AMP or URA data for the Subject Drugs means that California was in possession of "the actual prices at which Sandoz's drugs were available to retail pharmacies in the marketplace on a quarterly basis from 1991 onward." (Sandoz SJ Br. 8.) Sandoz further argues that by employing a simple formula, California "was easily [able to] determine"—and in fact *did* determine—"the AMP for [any] given drug." (Local

Rule 56.1 Statement of Undisputed Facts in Support of Defendant Sandoz Inc.'s Motion for Summary Judgment ("Sandoz SOF") ¶¶ 10-11 (emphasis added).) Accordingly, reasons Sandoz, California not only knew the actual prices at which Sandoz sold its drugs to its pharmacy customers, but also knew of the spreads between those actual prices and the fraudulently inflated AWPs that it reported to the pricing compendia.

In reality, however, while Sandoz provided AMP data to California from 1991 through 1997 pursuant to a supplemental rebate agreement (*see*, Plaintiffs' Statement of Additional Facts in Opposition to Sandoz, Inc.'s Motion for Summary Judgment ("CA SOAF Sandoz") ¶ 1), and while California (like all states) did receive URA data from CMS pursuant to the rebate agreement between Sandoz and the federal government (Sandoz SOF ¶¶ 3-4, 7), at no time did California use this information in the manner suggested by Sandoz, nor was it required to do so. In fact, as shown below, California believed it could not legally do so. Most importantly, as explained below, Sandoz subscribed to an industry lobbying position which explicitly disavowed the reliability of AMPs as an indicator of actual market prices.

As testified to by various employees of California's Department of Health Care Services,[2] which administers Medi-Cal, the AMP data received from drug manufacturers (including Sandoz) pursuant to supplemental rebate agreements was first given to EDS[3] for procedural verifications. EDS would then load the AMP data into the rebate system to calculate the supplemental rebates. (CA SOAF Sandoz ¶ 2.) The AMP data received by California from

[2] The relevant period alleged in Plaintiffs' case runs from January 1, 1994 through December 31, 2004. Throughout that period, the Medi-Cal program ("Medi-Cal") was administered by the California Department of Health Services ("DHS"). Effective July 1, 2007, the California Department of Health Services was renamed the California Department of Health Care Services ("DHCS"), which continues to administer Medi-Cal. DHS and DHCS are herein used interchangeably, but refer to the same entity.

drug manufacturers was used *only* for the calculation of supplemental rebates. (CA SOAF Sandoz ¶ 3.)

California did not calculate AMPs from the URA data it received from CMS (CA SOAF Sandoz ¶ 4). Nor did it use AMPs or URA data in connection with discussions about reimbursement or in connection with policy decisions concerning reimbursement. (CA SOAF Sandoz ¶¶ 5-6.) California has always treated AMP data as confidential under federal law (42 U.S.C. § 1396r-8(b)(3)(D) (CA SOAF Sandoz ¶ 8), and understood during the relevant time period that using AMPs to establish a reimbursement formula would in fact breach the confidentiality afforded to AMPs under applicable federal law. (CA SOAF Sandoz ¶ 9.)

This Court held in *Mylan Labs*. that the possession of a manufacturer's URA data, from which a state Medicaid agency could purportedly "reverse engineer" AMPs for that manufacturer's products, is not sufficient to establish a government knowledge defense. *Mylan Labs.*, 608 F. Supp. 2d at 152. Sandoz attempts to distinguish such holding by arguing that: (1) California received AMPs directly from Sandoz, so no reverse engineering was necessary; (2) California could and did use URA data to calculate AMPs; and (3) unlike the situation in *Mylan Labs*., all of Sandoz's drugs are generic, thereby alleviating any ambiguity regarding alternative formulas for ascertaining AMPs for brand drugs. (Sandoz SJ Br. 8.) These purported distinctions are meritless.

First, as Sandoz itself admits, Sandoz provided its AMPs directly to California only until 1997. The time period involved in California's First Amended Complaint ("FAC") runs until 2004, meaning "reverse engineering" would have been necessary for most of the relevant time period. Second, as noted above, California did not reverse engineer AMPs from URA data based

[3] Electronic Data Systems ("EDS") was at all relevant times the fiscal intermediary contracted by DHCS to process Medi-Cal claims.

on the belief that AMPs were confidential under federal law. Third, the fact that *Mylan Labs.* addressed whether AMPs could have been determined for brand drugs from URA data is irrelevant, since Massachusetts also reimbursed for generic drugs, and certainly that portion of the holding in *Mylan Labs* controls the resolution of the same issue in the instant case.

In *Mylan Labs*, the defendants argued that because Massachusetts received URA data on defendants' products from CMS, Massachusetts had "actual direct knowledge that Wholesale Acquisition Costs ("WACs")[4] were not true market prices because officials could 'reverse engineer' the actual price paid based upon the [AMP] that manufacturers reported to the federal government." *Mylan Labs*., 608 F. Supp. 2d at 151. Massachusetts countered, in relevant part, that in light of the confidentiality of AMPs, the Commonwealth neither used nor believed it could use AMPs to set reimbursement rates. Further, while Massachusetts admitted "it would take only a few seconds to turn URAs into AMPs," such calculation was not performed until it began investigating the case. This Court agreed that the Commonwealth's possession of URA data and AMPs did not amount to the knowledge necessary for a government knowledge defense, stating: "…[E]ven if you didn't need Einsteinian quantitative skills to discover the fraud, the Commonwealth's failure to do so does not equate to government knowledge or approval." *Id*. at 152.

Analogously, in the instant case California did not reverse engineer the URA data it received on the Sandoz drugs to create AMPs, as it believed that to do so would breach the confidentiality afforded to AMPs under federal law. California did not include AMPs or URAs in any discussion or policy decision concerning reimbursement; nor did it compare AMPs or URAs with any other pricing information, including AWPs. (CA SOAF Sandoz ¶ 7.) Following

[4] The distinction between WAC and AWP for purposes of this Court's opinion in *Mylan Labs* concerning government knowledge is of no import, particularly since Sandoz makes the same argument in the pending motion as defendants did in *Mylan Labs,* save for referencing AWP in place of WAC.

this Court's holding in *Mylan Labs*, California's mere possession of URA data or AMPs does not equate to government knowledge or approval. Summary judgment on this issue must therefore be denied.

The caselaw cited by Sandoz in its pending motion does not help its position. For example, Sandoz cites *Am. Contract Servs. v. Allied Mold & Die, Inc*., 94 Cal. App. 4th 854 (2001) for the proposition that in an action under the CA FCA, the government's knowledge of the fraud effectively negates the falsity element required by the CA FCA. (Sandoz SJ Br. 4.) In *Am. Contract Servs*., an unsuccessful bidder on a state contract for infant drinking cups filed a CA FCA suit against the winning competitor, whose bid had not been in compliance with all technical requirements. In upholding the dismissal of the action by the Attorney General (who had earlier intervened), the court found that the state itself had abandoned the competitive bidding process to enter into the contract with defendant. The court stated that "[T]here cannot be a knowing presentation of a false claim where the government is fully aware of the facts surrounding the claim and approves it." *Id*. at 864. The court concluded by stating: "The government alone decided to abort the bidding process and invoke sole sourcing to purchase the cups from [the defendant]. Even if this was an improper contracting practice, [the defendant] did nothing more than acquiesce in the government's contracting proposal." *Id*. at 865. In *Am. Contract Servs.*, unlike the instant case, the government itself explicitly initiated the deviation from state regulations.

Sandoz also cites to the case of *United States ex rel. Durcholz v. FKW Inc*., 189 F.3d 542 (7th Cir. 1999). There, an unsuccessful bidder for a dredging project brought an action against the winning contractor for the manner in which defendant billed the government for work on the project. In affirming summary judgment for defendant, the court addressed the issue of government knowledge as follows:

> "From the start, [the government's] officials were more interested in speed than cost and made their decisions in accordance with these priorities. They classified the project as a performance specification in order to expedite the bidding, knowing that the UPB did not contain dredging line-items. They later *directed* FKW to modify its proposal to match the Midwest bid and *told* FKW to resubmit its invoices without the excavation line-items. Thus, the government not only knew that FKW's proposal and invoices contained excavation line-items, it *directed* FKW to use those pricing numbers. In essence, then, Durcholz is alleging that the government was defrauded by the very activities that its agents *ordered*. We decline to hold FKW liable for defrauding the government by following the government's explicit directions."

Id. at 545 (emphasis added).

Finally, as this Court held in *Mylan Labs*., 608 F. Supp. 2d at 148:

> "Even those cases that have found government knowledge to negate the element of falsity have required that the government possess knowledge of the actual true facts of the claim, not simply knowledge that the claim is generally false; some have further required that the government actually approve of those true facts…Further, these cases also seem to rely on the fact that the government *approves* of the false claim, finding no falsity only where it is alleged that the government was defrauded by the very activities its agents ordered and that the defendant defrauded the government by following the government's explicit directions."

When these cases are compared to the "facts" alleged by Sandoz in the pending motion (i.e., Sandoz's AMP information from 1991 through 1997, and CMS URA data), it is clear that Sandoz has failed to establish the appropriate level of government knowledge sufficient to allow this Court to determine that, as a matter of law, Plaintiffs' claims under the CA FCA should be dismissed. Sandoz never instructed or informed California about the mega-spreads on its AWPs. Sandoz's motion for summary judgment must therefore be denied.

B. AMPs Do Not Represent an Accurate Reflection of Market Prices

In the pending motion, Sandoz represents to this Court that as the result of receiving AMPs for Sandoz's drugs, or URA data from CMS, California was in possession of "the actual prices at which Sandoz' drugs were available to retail pharmacies in the marketplace," and "at all times had full knowledge of the price at which Sandoz's drugs were actually available to

pharmacists." (Sandoz SJ Br. 8-9.) It is apparent, however, that not even Sandoz actually believes this.

Sandoz is a member of the Generic Pharmaceutical Association ("GPhA"), a trade association whose members include generic drug manufacturers, including Sandoz. The mission of GPhA is to promote the interests of the generic pharmaceutical industry. A representative from Sandoz, traditionally its CEO, has always sat on the Board of Directors of GPhA, and on the GPhA Executive Committee. (CA SOAF Sandoz ¶ 18.) In 2005 GPhA created the Medicaid Task Force (also called the AMP Task Force), in response to the proposed federal Deficit Reduction Act. The purpose of the Medicaid Task Force was to address the concerns of the generic pharmaceutical industry about the proposed use of AMPs as the basis for (a diminished level of) pharmacy reimbursement. (CA SOAF Sandoz ¶ 14.) Sandoz was a member of GPhA's Medicaid Task Force. (CA SOAF Sandoz ¶¶ 14, 20.)

In October 2005 GPhA sent a letter to Charles Grassley, Chairman, Committee on Finance, and to Max Baucus, Ranking Minority Member, Committee on Finance, for the purpose of cautioning the United States Senate Committee on Finance about using AMPs as the basis to calculate pharmacy reimbursement. According to GPhA, AMPs did not represent an accurate reflection of true market prices. (CA SOAF Sandoz ¶ 12.) In February 2007 GPhA sent a letter to CMS, stating that AMPs are easily misinterpreted "when payers, state agencies and consumers rely on AMPs to indicate actual prices available in the marketplace." (CA SOAF Sandoz ¶ 13.) Sandoz agreed with the position taken by GPhA that "AMP is mistakenly perceived as an indicator of market prices, however, it bears little relevance to market price." (CA SOAF Sandoz ¶ 21.)

In 2007, attorneys for GPhA prepared a "white paper" for California, the purposes of which were to explain GPhA's position that AMPs were not an adequate basis upon which to

calculate pharmacy reimbursement, to talk about the limitations of AMPs, and to express concerns about the confidentiality of AMPs. (CA SOAF Sandoz ¶ 15.) The white paper conveyed the position of GPhA that using AMPs would not be an accurate way of calculating the price charged by a manufacturer to consumers. (CA SOAF Sandoz ¶ 18.) Before it was sent to California, the white paper was reviewed by members of the GPhA State Government Affairs Committee. Sandoz was a member of the State Government Affairs Committee. (CA SOAF Sandoz ¶ 16.)

In May 2007, a representative of Defendant Mylan met with Dr. Kevin Gorospe, Chief of the Medi-Cal Pharmacy Policy Unit at DHCS. The meeting included a discussion about AMPs in which the Mylan representative described how and why AMPs were a poor basis for reimbursement because they were "unreliable." (CA SOAF Sandoz ¶ 10.) At this meeting the Mylan representative presented Dr. Gorospe with the GPhA white paper. (CA SOAF Sandoz ¶ 11.)

Plaintiffs respectfully submit that it is disingenuous for Sandoz to adhere to GPhA's position regarding the unreliability of AMPs while representing to this Court that AMPs provided California with "knowledge" of market prices. Moreover, the reliability of AMPs is further compromised by the fact that a manufacturer such as Sandoz has the ability to change or restate its AMP data for a period of five calendar quarters following the period it initially provided the data to California. (CA SOAF Sandoz ¶ 4.) It would have been impracticable and useless for California to attempt to ascertain actual acquisition prices by using AMP data that was subject to change at the discretion of the manufacturer. Sandoz's contrary suggestion is simply untenable.

C. Sandoz Has the Scienter Necessary To Hold It Liable Under the CA FCA

In its pending motion, Sandoz claims that it could not have acted with the scienter required for a violation under the CA FCA due to California's alleged knowledge of its fraudulent prices and the fact that Sandoz "informed the government of the very facts on which the government claims to have been defrauded." (Sandoz SJ Br. 4.) Both of these claims are specious and, as such, cannot support or justify the granting of Sandoz's motion for summary judgment.

Regarding the government knowledge claim, this Court stated in *Mylan Labs*., 608 F. Supp. 2d at 149:

> "Similarly, while some courts have found that government knowledge can prevent the defendant from forming the requisite state of mind (knowing that the claim is false or fraudulent), they have done so only where the government's knowledge as to the true facts is extensive and in some cases where the government has actively approved of the underlying facts. According to the Tenth Circuit, "there may…be occasions when the government's knowledge of or cooperation with a [defendant's] actions is so extensive that the [defendant] could not as a matter of law possess the requisite state of mind to be liable under the FCA." *Shaw v. AAA Eng'g & Drafting, Inc*., 213 F.3d 519, 534 (10th Cir. 2000). Likewise, the Fourth Circuit held that "the government's knowledge of the facts underlying an allegedly false record or statement can negate the scienter required for an FCA violation"; specifically, that the government's "*full knowledge of the material facts* underlying [a defendant's representations]…negates any knowledge that [the defendant] had regarding the truth or falsity of those representations." *Becker*, 305 F.3d at 289 (emphasis added). For instance, where the defendant and the government "so completely cooperated and shared all information," claims could not be knowingly false. *United States ex rel. Butler v. Hughes Helicopters, Inc*., 71 F.3d 321, 327 (9th Cir. 1995).

The only "knowledge" on the part of California pointed to by Sandoz in its pending motion is the receipt by California of Sandoz's AMPs from 1991 through 1997, and the receipt of URA data from CMS on the Sandoz drugs for the period covered in the FAC.[5] However, as

[5] Sandoz does make reference at page 8 of its Brief in Support of its Motion for Summary Judgment to the "wealth of information known to California regarding the generic drug marketplace in general and the pricing "spreads" in that marketplace between AWP and actual transaction prices." However, as noted in the Brief, this more general

this Court held in *Mylan Labs*, possession of AMPs (or URA data from which AMPs could be calculated), does *not* equate to government knowledge or approval. *Mylan Labs*., 608 F. Supp. 2d at 152.

Regarding its "disclosure" argument, Sandoz apparently takes the position that by providing California with AMPs from 1991 through 1997 pursuant to the supplemental rebate contract between itself and California, it was so open and cooperative with California concerning the difference between its fraudulently inflated AWPs and providers' actual acquisition costs for its drugs that it could not possibly have acted with the requisite scienter required under a CA FCA claim.

In support of this position, Sandoz cites *United States ex rel. Costner v. U.S.*, 317 F.3d 883 (8th Cir. 2003). There, plaintiff brought an action under the FCA alleging that defendants concealed operational problems and regulatory violations, thereby submitting false claims for payment under contracts with the EPA. In affirming the district court's granting of summary judgment for defendants, the court stated that: "[A] contractor that is open with the government regarding problems and limitations and engages in a cooperative effort with the government to find a solution lacks the intent required by the Act." *Id*. at 888. The court further held that:

> "The record contains extensive documentation revealing the inspections conducted by the EPA, the reports sent to the EPA by the defendant contractors and on-site EPA personnel…The EPA did not consider the operational difficulties encountered by the defendants to be contractual violations. The EPA worked with the defendants to resolve problems as they arose and to improve the efficiency of the process."

Id. at 887.

Here, in explicit contrast, Sandoz has admitted that it did not report its transactional prices, or any average or compilation of these prices, to the pricing compendia or to California as

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"government knowledge" argument is made in Defendants' joint motion for partial summary judgment, and will not be directly addressed here.

its products' AWPs or otherwise (CA SOAF Sandoz ¶ 24); that there was no fixed or predictable relationship between the AWPs that Sandoz reported to the pricing compendia and the prices at which its products were sold to the retail class of trade (CA SOAF Sandoz ¶ 25); and that Sandoz was aware of or on notice that California reimbursed providers for pharmaceutical products based on the reported AWPs for those products (CA SOAF Sandoz ¶ 26.) Further, Sandoz has never explained to Medi-Cal the difference between its reported AWPs and actual provider acquisition costs for its drugs. (CA SOAF Sandoz ¶ 22.)

In addressing this issue, this Court in *Mylan Labs*., 608 F. Supp. 2d 127, 149 (D. Mass. 2008) stated:

> "Similarly, some courts have found that where the defendant has disclosed the true facts underlying a claim, the defendant cannot be said to know that the claim is false. As one court put it, a defendant's disclosure…to the government is relevant, not because government knowledge of a misrepresentation shields a [defendant] from liability, but because evidence of disclosure may "point[] persuasively away from any conclusion that [the defendant] made a knowing misrepresentation." In other words, disclosure…may establish that the defendant did not "knowingly" submit false claims…*United States v. Newport News Shipbuilding Inc*., 276 F. Supp. 2d 539, 564 (E.D. Va. 2003)."

This Court further stated in *Mylan Labs* that the granting of a summary judgment on the issue of a party's scienter is unusual. *Mylan Labs*., 608 F. Supp. 2d at 154. This case illustrates that statement. Indeed, based upon the "evidence" produced in support of the instant motion, Sandoz's claim that it acted without the requisite scienter amounts to legal fiction. The pending motion for summary judgment should be denied.

II. DEFENDANT SANDOZ IS NOT ENTITLED TO PARTIAL SUMMARY JUDGMENT ON THE BASIS OF THE STATUTE OF LIMITATIONS

A. Absent "Discovery" by the State Attorney General, a CA FCA Claim Involving State Funds Must Be Filed No More Than 10 Years After the Date on which the Violation Is Committed.

To be timely, a claim under the CA FCA must be filed within three years "after the date of discovery by the official of the state or political subdivision charged with responsibility to act in the circumstances or, in any event, no more than 10 years after the date on which the violation of Section 12651 is committed." CAL. GOV'T CODE § 12654(a); *Debro v. Los Angeles Raiders*, 92 Cal. App. 4th 940, 947 (2001). "The purpose of the [CA FCA] is to protect the public treasury and the taxpayer. [Citation.] Accordingly, the act must be construed broadly to give the widest possible coverage and effect to the prohibitions and remedies it provides. [Citation.]" *County of Kern v. Sparks*, 149 Cal. App. 4th 11, 17 (2007). Thus, absent "discovery" of the violation at issue, a CA FCA claim is timely if filed within 10 years after the date such violation occurred.[6]

Although the CA FCA was modeled after the federal False Claims Act (31 U.S.C. § 3729 et seq.), *Rothschild v. Tyco Internat.* (U.S.), Inc., 83 Cal. App. 4th 488, 494 (2000), "the language of the federal statute of limitations differs significantly" from that of Section 12654(a). *State of California ex rel. Hindin v. Hewlett-Packard Co*. ("*Hindin*"), 153 Cal. App. 4th 307, 318 (2007); *Debro*, 92 Cal. App. 4th at 949. For example, under the federal statute, the limitations period begins when material facts were "known or reasonably should have been known" (31 U.S.C. § 3731(b)(2)), whereas the California statute of limitations commences upon "discovery."

[6] Under the continuing accrual doctrine, "[w]hen an obligation or liability arises on a recurring basis, a cause of action accrues each time a wrongful act occurs, triggering a new limitations period. [Citation.] The continuing accrual rule has been applied in a variety of actions involving the obligation to make periodic payments under California statutes or regulations." *Hogar Dulce Hogar v. Community Development Commission*, 110 Cal. App. 4th 1288, 1295 (2003) (citing inter alia, *Howard Jarvis Taxpayers Assn. v. City of La Habra*, 25 Cal. 4th 809, 818-825 (2001) (doctrine applied to action involving taxes). In the present case, each false AWP report gave rise to a new claim.

Hindin, 153 Cal. App. 4th at 318; Debro, 92 Cal. App. 4th at 949; CAL. GOV'T CODE § 12654(a). California courts, therefore, have found federal cases interpreting federal False Claims Act language to be unpersuasive in interpreting the CA FCA's limitations provisions. *Hindin*, 153 Cal. App. 4th at 318; *Debro*, 92 Cal. App. 4th at 949.

Under the CA FCA, "discovery" occurs when the responsible government official "either knows of the false claim or knows of facts which would lead a reasonably prudent person to suspect it." *Debro*, 92 Cal. App. 4th at 953. The "plain and commonsense" interpretation of section 12654 is that the limitations period begins on "the date of discovery" by a state official such as the Attorney General, not the private qui tam plaintiff. *Hindin*, 153 Cal. App. 4th at 314; see CAL. GOV'T CODE § 12654(a). Accordingly, for purposes of Defendant's motion, this Court must consider, in a manner consistent with California courts' interpretations of section 12654, the extent and timing of the information known to "the Attorney General, who has responsibility to act to protect the public fisc from false claims." *See Hindin*, 153 Cal. App. 4th at 315; *accord*, *id.* at 319 (examining when the Attorney General was aware of the claim); *see also*, *Debro*, 92 Cal. App. 4th at 951.

In the present case, there is no evidence to establish as a matter of law that, prior to August 1999, California knew—or knew facts which would have led a reasonably prudent person to suspect—that among the more than 550 generic drug manufacturers whose products were reimbursed by Medi-Cal, Sandoz was falsely reporting the AWPs for the particular drugs at issue in this action. Absent such "discovery" within the meaning of Section 12654(a), the State's claims against Sandoz for conduct that occurred prior to August 1999 cannot be barred by the statute of limitations.

B. Defendant Sandoz Has Not Irrefutably Established that California "Discovered" the Alleged Conduct Prior to August 1999.

"Summary judgment is not appropriate unless only one reasonable inference can be drawn from undisputed facts." *Cleveland v. Internet Specialties West, Inc*., 171 Cal. App. 4th 24, 31 (2009); *accord, Betz v. Trainer Wortham & Co*., 519 F.3d 863, 871-72 (9th Cir. 2008) ("Summary judgment is appropriate only when uncontroverted evidence irrefutably demonstrates plaintiff discovered or should have discovered the fraudulent conduct"); *see also, Celotex Corp. v. Catrett,* 477 U.S. 317, 322-23 (1986) (Summary judgment is proper only where there is "no genuine issue as to any material fact").

The statute of limitations provides an affirmative defense for which the defendant bears the burden of proof. *Norgart v. Upjohn Co*., 21 Cal. 4th 383, 396 (1999). Although the responsible public official need not know "every detail or determine the particular legal theory the plaintiff would later assert" to trigger the statute of limitations, *Debro,* 92 Cal. App. 4th at 955, Sandoz has not presented any undisputed facts which would irrefutably establish, drug-by-drug, that the Attorney General either knew Sandoz falsely reported its AWPs or knew "facts which would lead a reasonably prudent person to suspect it." *See Debro*, 92 Cal. App. 4th at 953. The record in this case therefore does not permit judgment as a matter of law, as it presents genuine issues of material fact regarding the extent and timing of information available to the Attorney General concerning each drug at issue in this action, and whether such information was sufficient to trigger the statute of limitations under California law.

In its brief in support of this motion, Sandoz states: "California was aware as early as 1986 that published AWPs were substantially higher than providers' costs to acquire drugs." It supports this "fact" with a general reference to California's Supplemental Responses to Defendants' First Set of Interrogatories, dated August 21, 2008. (Sandoz SJ Br. 11, n.5.)

Sandoz has grossly mischaracterized this "fact." The actual statement contained in California's Supplemental Response is quite different:

> In the mid to late 1980's, Plaintiff became aware through OIG reports that some providers could sometimes obtain some prescription drugs at approximately 15% less than reported AWPs. However, Plaintiff contends that the very large mega-spreads at issue in this case were not generally known or understood. Plaintiff contends that there might have been some general awareness that some AWPs were inflated to some degree. However, Plaintiff contends the identity and extent of the mega-spreads on specific drugs were not widely known or identified until the investigation by the Office of the Attorney General.

(Supplemental Response to Interrogatory Number 19 of California's Supplemental Responses to Defendants' First Set of Interrogatories, dated August 21, 2008, at 4.)

Sandoz also claims, "California was specifically aware of the difference between AWP and actual average transaction prices at the retail level for each and every Sandoz NDC from 1991 to 1997 and the URAs for each NDC at all other times." (Sandoz SJ Br. at 11.) Not surprisingly, Sandoz cannot cite to *any* evidence in support of this false assertion.

Only two documents are offered by Sandoz to support its statute of limitations defense: (1) the 1996 HHS-OIG publication entitled "Review of Pharmacy Acquisition Costs for Drugs Reimbursed under the Medicaid Prescription Drug Program of the California Department of Health Services," and (2) the July 1998 *qui tam* complaint in this action. (Sandoz SJ Br. 2-5, referring to Defs. Jt. SOF ¶¶ 32, 60.) Neither document supports Sandoz's position.

At best, the HHS-OIG publication revealed that some providers could sometimes obtain some generic prescription drugs at a cost far less than the reported AWPs, resulting in an average pharmacist invoice price for generic drugs at 41.5 percent below AWP. The publication neither affirmatively averred nor compelled the conclusion that any particular manufacturer had engaged in fraudulent conduct or that any particular drug's price had been fraudulently inflated. The publication made no specific reference to Sandoz or to any of the drugs it manufactured—let alone any of the subject drugs at issue herein. And the publication neither revealed nor

reasonably suggested that the reported AWPs of these subject drugs were grossly inflated and unrelated to actual market prices. (CA Resp. Defs. SOF ¶ 32.)

Similarly, while the 1998 *qui tam* complaint alerted the Attorney General to conduct of particular pharmaceutical manufacturers and of specific drug products, it did not identify Sandoz or any of the drugs it manufactured. (CA Resp. Defs. SOF ¶ 60.)

Accordingly, nothing submitted by Sandoz establishes, as a matter of law, that California "discovered" the facts underlying the pending false claim allegations; genuine issues of material fact exist regarding the extent and timing of information available to the Attorney General concerning each drug at issue in this action, and whether such information was sufficient to trigger the statute of limitations under California law. Summary judgment on the basis of the defendant's affirmative defense should, therefore, be denied.

C. Defendant's Reliance on *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20 (D. Mass. 2007) is Misplaced

Defendant Sandoz suggests that this Court should find the statute of limitations bars California's claims prior to 1999, just as it held the Massachusetts third-party payors' pre-December 1997 claims to be untimely in *In re Pharm. Indus. Average Wholesale Price Litig*., 491 F. Supp. 2d 20 (D. Mass. 2007). However, this Court's determinations in the 2007 case followed a 20-day bench trial that included testimony from nearly 40 witnesses, *id.* at 30, while the instant matter is still at the summary judgment stage. Indeed, on summary judgment motions in a subsequent Massachusetts drug-pricing case against Mylan, this Court declined to determine the triggering event(s) of the limitations period, stating, "[t]he Court will have to address statute of limitations—what the government should have known, and when it should have known it—drug-by-drug." *Mylan Labs*., 608 F. Supp. 2d at 160.

Further, in *In re Pharmaceutical. Indus. Average Wholesale Price Litig*., 491 F. Supp. 2d 20, this Court explained:

> When Congress passed the Balanced Budget Act of 1997, it put third party payors on inquiry notice that many AWPs were not true prices paid by physicians and pharmacies to acquire the pharmaceuticals. The class period ends in 2003 when Congress passed the Medicare statute setting new reimbursement benchmarks.

Id. at 31-32.

This Court made its findings, however, upon applying Massachusetts law, specifically a statute regulating private business practices,[7] *see id.* at 75-76, not false claims act violations, *see id.* at 29. In contrast, "[t]he ultimate purpose of the [CA FCA] is to protect the public fisc." *State of California v. Altus Finance*, 36 Cal. 4th 1284, 1296-97 (2006). *See also, Levine v. Weis*, 68 Cal. App. 4th 758, 764-65 (1998) (distinguishing California Unfair Practices Act and Cartwright Act cases from CA FCA cases), disapproved on other grounds in *Wells v. One2One Learning Foundation*, 39 Cal. 4th 1164, 1197 (2006). Given its clear public purpose, *see Pulcifer v. County of Alameda*, 29 Cal. 2d 258, 262 (1946), which was "obviously . . . to prevent fraud on the public treasury, [California Government Code] section 12653 plainly should be given the broadest possible construction consistent with that purpose." *Altus Finance*, 36 Cal. 4th at 1299.

Finally and most significantly, the statute of limitations issue in the 2007 case concerned whether the plaintiffs were entitled to tolling of a concededly-expired limitations period—a showing for which the plaintiffs bore the burden. *See In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 75-76 (citing *Saenger Org., Inc. v. Nationwide Ins. Licensing Assocs., Inc.*, 119 F.3d 55, 65 (1st Cir. 1997)).

[7] "[T]he purpose of [Mass. Gen. Laws] Chapter 93A [was] to 'encourage more equitable behavior in the marketplace and impose liability on persons seeking to profit from unfair practices' . . ." *In re Pharmaceutical Indus. Average Wholesale Price Litig*., 582 F.3d 156, 194 (1st Cir. 2009); *see also, Purity Supreme, Inc. v. Attorney General*, 380 Mass. 762, 776, 407 N.E. 2d 297 (Mass. 1980) (quoting *Lowell Gas Co. v. Attorney General*, 377 Mass. 37, 51, 385 N.E. 2d 240 (Mass. 1979)).

In contrast, here, it is Defendant's burden to affirmatively establish a statute of limitations defense. *Norgart*, 21 Cal. 4th at 396; *see also, United States v. Carter*, 906 F.2d 1375, 1378 (9th Cir. 1990). "Resolution of the statute of limitations issue is normally a question of fact." *Fox v. Ethicon Endo-Surgery, Inc.*, 35 Cal. 4th 797, 810 (2005); *accord, In re Lupron Mktg. & Sales Practices Litig.*, 295 F. Supp. 2d 148, 183 (D. Mass. 2003) ("Whether a plaintiff knew or should have known of an injury so as to trigger the running of a statute of limitations is, with rare exception, a jury issue"). Likewise, a determination of whether reasonable diligence was exercised by a plaintiff in discovering a violation "is a question of fact for the court or jury to decide." *Cleveland*, 171 Cal. App. 4th at 31 (internal quotation marks and citations omitted).

This case does not present a "rare exception" to the general rule. Sandoz has not presented undisputed facts which would irrefutably establish, drug-by-drug, that the Attorney General either knew that Sandoz falsely reported its AWPs, or knew "facts which would lead a reasonably prudent person to suspect" such false reporting. *See Debro*, 92 Cal. App. 4th at 953. Because, as discussed above, genuine issues of material fact remain as to the extent, the timing, and the sufficiency of the information available to the Attorney General concerning each drug at issue in this action, summary judgment on the basis of the defendant's affirmative statute of limitations defense must be denied.

Dated: December 21, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on December 21, 2009, a copy to Lexis-Nexis for posting and notification to all parties.

/s/ Steven U. Ross
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